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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/507,106	09/10/2004	Tsukaya Hirokazu	47232-5010-00-US	4857

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EXAMINER	
BAUM, STUART F	

ART UNIT	PAPER NUMBER
1638	

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06/27/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/507,106	HIROKAZU ET AL.	
	Examiner	Art Unit	
	Stuart F. Baum	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 March 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *30-38* is/are pending in the application.

4a) Of the above claim(s) *32 and 38* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *30,31,33-35 and 37* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *10 April 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *3/9/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☒ Other: *sequence search results (2)*.

DETAILED ACTION

1. Claims 30-38 are pending.

2. Applicant's election with traverse of Group I, claims 30-31, 33-35 and 37, including SEQ ID NO:1, 2, 3 and 4, wherein the polynucleotide is in sense orientation, in the reply filed on 4/2/2007 is acknowledged. The traversal is on the ground(s) that Group II should be recombined and searched with Group I (page 2 of Remarks, bottom paragraph).

This is not found persuasive because the claims of Group II are drawn to a second product. As specified in the restriction requirement mailed 3/7/2007, "Pursuant to 37 CFR 1.475(d), the ISA/US considers that where multiple products and processes are claimed, the main invention shall consist of the first invention. The Office considers nucleic acid molecules in sense and antisense orientation to be separate products.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-29 have been canceled.

Claims 32 and 38 are withdrawn from consideration for being drawn to non-elected inventions.

3. Claims 30-31, 33-35 and 37, including SEQ ID NO:1, and 2, nucleotides 51 to 1625 of SEQ ID NO:3, and SEQ ID NO:4, are examined in the present office action.

Claim Objection

4. Claims 33 and 37 are objected to for being drawn to a non-elected invention. Correction is requested.

Claim 34 is objected to for reciting "a polynucleotide" instead of --the polynucleotide--.

Claim 35, line 3, is objected to for reciting "a polynucleotide" instead of --the polynucleotide--.

Claim 30, line 13, is objected to for reciting "one a amino acid" instead of --one amino acid--.

Written Description

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 30-31, 33-35 and 37 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to a polynucleotide comprising a nucleotide sequence of SEQ ID NO:1, or wherein said polynucleotide is operably linked to a promoter in a forward direction, or method or plant comprising said polynucleotide.

The Office interprets "*a* nucleotide sequence of SEQ ID NO:1" to read on a large number of sequences because the Office interprets said recitation to encompass nucleotide sequences comprising any portion of SEQ ID NO:1 because of the article "*a*".

Applicants disclose the nucleotide sequence of SEQ ID NO:1 (sequence listing).

The Applicants do not identify essential regions of the protein encoded by SEQ ID NO:1, nor do Applicants describe any polynucleotide sequences that comprises any portion of SEQ ID NO:1 and that encode a protein with the same function as the protein encoded by SEQ ID NO:1.

The Federal Circuit has recently clarified the application of the written description requirement to inventions in the field of biotechnology. See University of California v. Eli Lilly and Co., 119 F.3d 1559, 1568, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). In summary, the court stated that a written description of an invention requires a precise definition, one that defines the structural features of the chemical genus that distinguishes it from other chemical structures. A definition by function does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is. The court goes on to say, "A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus." *See University of California v. Eli Lilly and Co.*, 119 F.3d 1559; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997).

Applicants fail to describe a representative number of polynucleotide sequences encoding a protein falling within the scope of the claimed genus of polynucleotides that comprise any portion of SEQ ID NO:1 and encode a protein with the same activity as the protein encoded by SEQ ID NO:1. Applicants only describe a single nucleic acid sequence of SEQ ID NO:1. Furthermore, Applicants fail to describe structural features common to members of the claimed genus of polynucleotides. Hence, Applicants fail to meet either prong of the two-prong test set forth by *Eli Lilly*. Furthermore, given the lack of description of the necessary elements essential

for the protein encoded by SEQ ID NO:1, it remains unclear what features identify said protein. Since the genus of proteins encoded by SEQ ID NO:1 has not been described by specific structural features, the specification fails to provide an adequate written description to support the breath of the claims.

Enablement

6. Claims 30-31, 33, 34-35 and 37 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claimed invention is not supported by an enabling disclosure taking into account the *Wands* factors. *In re Wands,* 858/F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988). *In re Wands* lists a number of factors for determining whether or not undue experimentation would be required by one skilled in the art to make and/or use the invention. These factors are: the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples of the invention, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, and the breadth of the claim.

The claims are drawn to a polynucleotide comprising a nucleotide sequence of SEQ ID NO:1, a nucleotide sequence encoding SEQ ID NO:2 or encoding SEQ ID NO:2 wherein one amino acid is deleted, substituted or added and its expression stimulates brassinosteriod biosynthesis and a nucleotide sequence comprising nucleotides 51-1625 of SEQ ID NO:3 or a

nucleotide sequence encoding SEQ ID NO:4 or encoding SEQ ID NO:4 wherein one amino acid is deleted, substituted or added and its expression stimulates brassinosteriod biosynthesis; or wherein said polynucleotide is operably linked to a promoter in a forward direction, or a plasmid comprising said polynucleotide, or method for changing the morphology of a plant or a plant, comprising said polynucleotide.

The Office interprets "*a* nucleotide sequence of SEQ ID NO:1" to read on a large number of sequences because the Office interprets said recitation to encompass nucleotide sequences comprising any portion of SEQ ID NO:1 because of the article "*a*".

Applicants disclose the nucleotide sequences of SEQ ID NO:1 and 3 and the protein sequences of SEQ ID NO:2 and 4 (sequence listing).

Applicants have not reduced to practice their invention. Applicants have not transformed a plant with said polynucleotide and produced a plant with a changed morphology. Applicants have not taught by way of disclosure or example how transforming a plant with said construct, wherein expression of said polynucleotide produces two expressed proteins that stimulate brassinosteriod biosynthesis, will produce a plant with a changed phenotype. One skilled in the art would have to perform additional trial and error experimentation to enable the claimed invention.

The state-of-the-art teaches transforming plants with nucleic acid molecules encoding proteins involved in brassinosteroid-assisted development produce unexpected results. Zhou et al (2004, The Plant Journal 40:399-409) teach overexpression of a *BRL1* cDNA driven by a constitutive CaMV 35S promoter, recapitulates the *bri1-5* suppression phenotypes (abstract).

Applicant has not provided examples or guidance for selecting a sequence out of the multitude of sequences that are encompassed by Applicant's broad claim language, that gives the expected results when transformed into a plant. Transforming plants with heterologous genes that are involved in plant development produce unpredictable results. Kano-Murakami et al (1993, FEBS 334:365-368) teach introducing the *Oryza sativa* homeobox 1 (OSH1) gene into tobacco. OSH1 is a rice homologue of the *Knotted-1* homeobox gene from maize and would be encompassed by Applicant's broad claim language. Kano-Murakami et al teach transgenic tobacco plants comprising the OSH1 gene display a "range of phenotypes which include abnormalities in leaf and petal shape as well as stem height and number" (page 365, right column, 1st paragraph).

Applicants have not disclosed how one makes or isolates any of the sequences that are encompassed by Applicants' broad claims. Applicants have not taught which regions of the respective polynucleotides can be used to amplify any of said polynucleotides or which regions can be used as a probe to isolate any of said polynucleotide sequences.

In the absence of guidance, undue trial and error experimentation would be required for one of ordinary skill in the art to screen through the multitude of non-exemplified sequences, either by using non-disclosed fragments of SEQ ID NO:1 as probes or by designing primers to undisclosed regions of SEQ ID NO:1 and isolating or amplifying fragments, subcloning the fragments to produce constructs in which SEQ ID NO:4 is expressed or SEQ ID NO:4 wherein one amino acid is deleted, substituted, or added and wherein SEQ ID NO:1 is expressed or any nucleotide sequence comprising any portion of SEQ ID NO:1 and wherein expression of both proteins stimulates brassinosteriod biosynthesis, and producing expression vectors and

transforming plants therewith, in order to identify those, if any, that when over-expressed produce a plant with a changed phenotype.

Therefore, given the breadth of the claims; the lack of guidance and examples; the unpredictability in the art; and the state-of-the-art as discussed above, undue experimentation would be required to practice the claimed invention, and therefore the invention is not enabled.

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 30-31 and 33 are rejected under 35 U.S.C. 102(b) as being anticipated by Kim et al (1998, Genes & Development 12:2381-2391).

The claims are drawn to a polynucleotide comprising a nucleotide sequence of SEQ ID NO:1, and a nucleotide sequence of SEQ ID NO:3 or a nucleotide sequence encoding SEQ ID NO:4, or wherein said polynucleotide is operably linked to a promoter in a forward direction, or a plasmid comprising said polynucleotide.

The Office interprets "*a* nucleotide sequence of SEQ ID NO:1" to read on a large number of sequences because the Office interprets said recitation to encompass nucleotide sequences comprising any portion of SEQ ID NO:1 because of the article "*a*".

Kim et al disclose a genomic sequence from Arabidopsis encoding the ROTUNDIFOLIA3 (ROT3) protein, wherein the nucleotide sequence comprises nucleotides 51 to 1625 of SEQ ID NO:3 and wherein the nucleotide sequence encodes SEQ ID NO:4 (sequence search results included) and wherein the sequence of Kim et al also comprises a nucleotide sequence of SEQ ID NO:1, given the Office's interpretation of "*a* nucleotide sequence of SEQ

ID NO:1" as discussed above. Kim et al disclose said nucleotide sequence was isolated by plasmid rescue and comprises a promoter and is contained within a plasmid (pages 2388-2389, Material and methods) and as such, Kim et al anticipate the claimed invention.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

8. Claims 30, 31, 34, 35 and 37 are directed to non-statutory subject matter. This rejection is made because the claims are drawn to "A polynucleotide" which does not indicate that the "hand of man" was involved in the invention. Amending the claim to recite "isolated" will obviate the rejection.

9. No claims are allowed.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stuart F. Baum whose telephone number is 571-272-0792. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached at 571-272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

Stuart F. Baum Ph.D.
Primary Examiner
Art Unit 1638
June 15, 2007

STUART F BAUM, PH.D
PRIMARY EXAMINER